



CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Food and Drug Administration  
7200 Lake Ellenor Drive  
Orlando, FL 32809

WARNING LETTER

FLA-98-08

November 18, 1997

John H. Flynn, Responsible Head  
Palm Beach Blood Bank, Incorporated  
933 45th Street  
West Palm Beach, Florida 33407

Dear Mr. Flynn:

During an inspection of your donor center located at 3123 Lake Worth Road, Lake Worth, Florida, on November 4, 1997, Investigator Philippe L. Noisin documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, and the Current Good Manufacturing Practice (CGMP) regulations for blood and blood components [Title 21, Code of Federal Regulations, Part 606 (21 CFR 606)] as follow:

1. Failure to maintain complete and adequate written standard operating procedures that reflect current blood bank operations [21 CFR 606.100(b)] in that:
  - Written procedures are in disarray in that multiple versions of your Technical Policy Procedures and indexes (outdated and current) are kept in your procedure manual and current procedures are not kept in their proper locations.
  - Current procedures such as "PHLE003" (Collection of Blood using Balance Scales) revised 5/12/97, and "PHE012" (Labeling of Pheresis Component), revised 9/16/96, could not be located during the inspection.
2. Failure to maintain equipment in adequate working condition for which they are designed to perform and/or in a state of calibration [21 CFR 606.60(a)] in that:
  - There is no documentation that a temperature recorder (Serial Number 229665) used for the monitoring of the platelet storage area has been calibrated since 11/13/91.

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- The microhematocrit instrument was used even though quality control records showed several out of specification results of the HCT standard reagent.
  - No periodic alarm check of the storage refrigerator has been conducted since 12/96. The chart showed at least two high temperature readings with no notation that the alarm worked.
3. Failure to assure that personnel are adequately trained and/or supervised in the performance of their assigned duties [21 CFR 606.20(a)&(b)] in that:
- Repeated out of specification microhematocrit calibration results were not noted by a supervisor and these failures were not investigated to determine the cause.
  - A supervisor was not aware of your requirement to conduct a periodic alarm check of the storage refrigerator.
  - A phlebotomist failed to determine and/or assure that a donor had read the AIDS educational material in accordance with your Technical Policy Procedure.
  - No documentation is available to show that personnel are familiar with and/or received adequate training regarding revised written procedures.

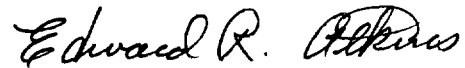
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with the Act and the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in administrative action, including license suspension and/or revocation, or regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

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Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

A handwritten signature in cursive script, reading "Edward R. Atkins". The signature is written in dark ink and is positioned above the typed name.

Edward R. Atkins  
Acting Director  
Florida District